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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,043	10/13/2005	Xin Lu	5585-69856-01	6728

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EXAMINER	
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ART UNIT	PAPER NUMBER
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/522,043	LU ET AL.	
	Examiner	Art Unit	
	Sean E. Aeder	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8,11-14 and 55-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 8, 11-14, and 55-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

The Amendments and Remarks filed 8/1/07 in response to the Office Action of 5/02/07 are acknowledged and have been entered.

Claims 55-60 have been added by Applicant.

Claims 1-3, 8, 11-14, and 55-60 are pending.

Claims 1, 2, and 13 have been amended by Applicant.

Claims 1-3, 8, 11-14, and 55-60 are currently under examination.

The following office action contains new rejections necessitated by amendments.

Objections Withdrawn

The objection to the specification is withdrawn.

Rejections Withdrawn

The rejection of claims 2 and 3 under 35 U.S.C., first paragraph, is withdrawn. However, it is noted that claims 1, 8, and 11-14 remain rejected under 35 U.S.C. 112, first paragraph.

Response to Arguments

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 8, and 11-14 remain rejected and newly added claims 55 and 59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons stated in the Office Action of 5/2/07 and for the reasons set-forth below.

The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, the claims are inclusive of: (1) a genus of isolated nucleic acid molecules which encode a polypeptide wherein said polypeptide is a fragment of the polypeptide set-forth in SEQ ID NO:8 having at least 85% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO:8, wherein the polypeptide inhibits the apoptotic activity of p53; (2) a genus of isolated nucleic acid molecules which encode a polypeptide wherein said polypeptide is a fragment of the polypeptide set-forth in SEQ ID NO:8 having at least 90% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO:8, wherein the polypeptide inhibits the apoptotic activity of p53; (3) and a genus of nucleic acid molecules encoding polypeptides having at least 95% sequence identity with residues 128-224 of SEQ ID NO:8. However, the written description in this case only provides a written description of isolated nucleic acid molecules which encode a polypeptide wherein said polypeptide is a fragment of the polypeptide set-forth in SEQ ID NO:8 having at least 95% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO:8, wherein the polypeptide inhibits the apoptotic

activity of p53. The specification does not disclose, and the art does not teach, a representative number of the nucleic acid variants broadly encompassed by the claims.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common to that genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus."

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d, 2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The instant specification fails to provide sufficient descriptive information, such as definitive structural or functional features that are common to the genera. That is, the specification provides neither a representative number of nucleic acid sequences that encompass the genera nor does it provide a description of structural features that are common to the genera. Further, in regards to genera encompassing variants, Applicant is directed to Example 13 of the Synopsis of Application of Written Description Guidelines (http://www.uspto.gov/web/menu/written.pdf), which addresses claims drawn to a genus of polypeptide variants. Example 13 states that even when a specification discloses

that changes which produce variants are routinely done in the art, the specification and the claims do not provide any guidance as to precisely what changes should be made. Structural features that could distinguish the compounds of the claimed genus from others not encompassed by the genus are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed. However, it is noted that in view of Example 14 of the Synopsis of Application of Written Description Guidelines, claims drawn to variants sharing a recited function *and* a sequence that has at least 95% sequence identity to a particular sequence are not included in this rejection. Since the disclosure fails to describe common attributes or characteristics that identify members of the genera, and because the genera are highly variant, the disclosure of amino acid residues 128-224 of SEQ ID NO:8 is insufficient to describe the genera. Thus, one of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe and enable the genera as broadly claimed.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genera, and

therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

In the reply of 8/1/07, Applicant amended the claims and argues that the claimed nucleic acid molecules each encode polypeptides which share the common structure of having at least 85% sequence identity with amino acid residues 128-224 of SEQ ID NO:8. Applicant further points-out that the specification provides general guidance of how one could make a variant nucleic acid molecule. Applicant further points-out that the specification states that polypeptides which share the common structure of having at least 85% sequence identity with amino acid residues 128-224 of SEQ ID NO:8 are part of the invention.

The amendments to the claims and the arguments found in the reply of 8/1/07 have been carefully considered, but are not deemed persuasive. In regards to the

argument that the claimed nucleic acid molecules each encode polypeptides which share the common structure of having at least 85% sequence identity with amino acid residues 128-224 of SEQ ID NO:8, "at least 85% sequence identity with amino acid residues 128-224 of SEQ ID NO:8" is a similarity and not a *common* structure.

In regards to the argument that the specification provides general guidance of how one could make a variant nucleic acid molecule and the specification states that variant nucleic acid molecules are part of the invention, Applicant is directed to Example 13 of the Synopsis of Application of Written Description Guidelines (http://www.uspto.gov/web/menu/written.pdf), which addresses claims drawn to a genus of polypeptide variants. Example 13 states that even when a specification discloses that changes which produce variants are routinely done in the art, the specification and the claims do not provide any guidance as to precisely what changes should be made. Structural features that could distinguish the compounds of the claimed genus from others not encompassed by the genus are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is needed. However, it is noted that in view of Example 14 of the Synopsis of Application of Written Description Guidelines, claims drawn to variants sharing a recited function *and* a sequence that has at least 95% sequence identity to a particular sequence are not included in this rejection. Further, adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolation. The compound itself is required. See *Fiers*

v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, 11-14 remain rejected and newly added claims 55-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al (WO 00/55175 A1; 9/21/00) for the reasons stated in the Office Action of 5/2/07 and for the reasons set-forth below.

The claims are drawn to nucleic acid molecules which encode a polypeptide, wherein said polypeptide is a fragment of the polypeptide sequence represented in SEQ ID NO:8 having at least 85% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO:8, wherein the polypeptide inhibits the apoptotic activity of p53. It is noted that a nucleic acid molecule "comprising" a sequence that encodes residues 128-224 of the amino acid sequence set-forth in SEQ ID NO:8 encodes a polypeptide, wherein said polypeptide is a fragment of the polypeptide sequence represented in SEQ ID NO:8 having at least 85% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO:8.

Rosen et al teaches a nucleic acid molecule encoding a polypeptide (SEQ ID NO:36) which is a 217 amino acid fragment of instant SEQ ID NO:8 (see attached

sequence comparison). Rosen et al further teaches said polypeptide would bind p53 (see page 14, in particular). Rosen et al further teaches said nucleic acid is isolated cDNA from a human (see pages 2, 4, and 373-374, in particular). Rosen et al further teaches expression vectors comprising said nucleic acid (pages 2 and 129-131, in particular). Rosen et al further teaches a cell transformed or transfected with said nucleic acid (page 131, in particular). Rosen et al further teaches pharmaceutical compositions comprising said nucleic acid (see pages 128-133, in particular). Although Rosen et al does not specifically teach said polypeptide inhibits the apoptotic activity of p53, the claimed polynucleotide appears to be the same as the prior art, absent a showing of unobvious differences. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the polynucleotide of the prior art does not possess the same functional characteristics of the claimed polynucleotide. In the absence of evidence to the contrary, the burden is on Applicant to prove that the claimed polynucleotide is different from that taught by the prior art and to establish patentable differences. See In re Best 562F .2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2nd 1992 (PTO Bd. Pat. App. & Int. 1989).

In the reply of 8/1/07, Applicant argues that the Rosen et al polypeptide is not a fragment of SEQ ID NO:8, as residues 191-217 of the Rosen et al polypeptide share no sequence similarity with SEQ ID NO:8. Applicant further states that the Rosen et al polypeptide does not have at least 85% sequence identity with residues 128-224 of SEQ ID NO:8.

The arguments found in the Reply of 8/1/07 have been carefully considered, but are not deemed persuasive. Applicant's arguments are not commensurate in scope with the claims. The claims are not drawn to a polypeptide; rather, the claims are drawn to a nucleic acid encoding a polypeptide. As stated above, a nucleic acid molecule "comprising" a sequence that encodes residues 128-224 of the amino acid sequence set-forth in SEQ ID NO:8 (such as the nucleic acid taught by Rosen et al) encodes a polypeptide, wherein said polypeptide is a fragment of the polypeptide sequence represented in SEQ ID NO:8 having at least 85% sequence identity with residues 128-224 of the amino acid sequence presented in SEQ ID NO:8.

New Rejections Necessitated by Amendments

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, 11-14, and 55-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and dependent claims 8, 11-14, and 55-58 are rejected because claim 1 recites: "An isolated nucleic acid molecule which encodes a polypeptide, wherein said polypeptide is a fragment of the polypeptide sequence represented in SEQ ID NO:8 having at least 85% sequence identity with residues 128-224 of the amino acid

sequence presented in SEQ ID NO:8". It is unclear how a polypeptide fragment of SEQ ID NO:8 can have less than 100% sequence identity to a sequence of SEQ ID NO:8.

Summary

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Aeder, Ph.D. whose telephone number is 571-272-8787. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEA

/Misook Yu/
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